

January 22, 2016

Dr. Stephen Ostroff, M.D.
Acting Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

RE: FDA Recommendations to Flush Certain Medications and Harmonize Federal Agency Messaging on Safe Medicine Disposal

Dear Commissioner Ostroff:

To protect public health and environmental quality, the signatories to this letter urge the FDA to work with the EPA, the DEA, and the White House Office of National Drug Control Policy to develop clear and consistent guidance to consumers on safe disposal of leftover household medications. **We call on the FDA to end its recommendation that certain medications be disposed by flushing, and to clarify that secure medicine take-back programs provide the best disposal method for leftover household medications.**

We appreciate the FDA's efforts to protect people from leftover medications that can be particularly harmful, even fatal, if abused or mistakenly consumed. However, the time has come for FDA to align its medicine disposal guidance with that of federal, state and local agencies who seek to protect both the public's health and our water quality.

Disposal of leftover medications by flushing contributes to pharmaceutical pollution that is harming aquatic ecosystems and entering our food web. Wastewater treatment plants are designed to remove human waste and easily degraded organics, and cannot effectively remove pharmaceuticals and other complex, synthetic chemicals. Because of this, some wastewater agencies have established laws, regulations, or guidance prohibiting flushing as a disposal method for pharmaceuticals. In these areas, FDA's recommendations infringe on wastewater districts' jurisdictional authority to protect public health.

While pharmaceuticals also enter wastewater through excretion, flushing of unwanted medication is a source that we have the ability and technology to control. The amount of leftover and expired medications in American homes is significant – estimated at 30-40% of all medications sold. It is critical to keep these pharmaceuticals from polluting our waterways by recommending secure and environmentally sound disposal through medicine take-back programs. Preventing pollution is always the most effective and least expensive option to protect public health and environmental health.

Many communities across the country now have medicine collection programs and the DEA's regulation to implement the Secure & Responsible Drug Disposal Act allows new options for take-back of prescription drugs that are controlled substances. We need clear and harmonized direction to the public and health practitioners on using medicine take-back programs, as well as ongoing efforts to increase access to secure medicine take-back programs in all communities.

Messages on medicine disposal are inconsistent between federal agencies and often in conflict with state and local regulations or guidance against flushing or trash disposal of leftover medications. This is confusing and frustrating for the public. Furthermore, the pharmaceutical industry takes advantage of inconsistencies in federal agency messaging to undermine efforts to establish local medicine take-back programs and regulations.

We therefore urge the FDA to end its “flush list” recommendation, and work to create a single disposal guidance that is endorsed by all federal agencies and consistently used on all federal websites and materials. The public should be directed to store medications securely in locked containers or cupboards, to use secure medicine take-back programs where available, never to flush medications, and to dispose of medications in the trash only as a last resort where allowed by local ordinances. We encourage adoption of the following, clear messages on safe medicine disposal:

1. To protect water quality, never flush unwanted medicine down any drain.
2. Use a community medicine take-back program for secure and safe medicine disposal. Check with local household hazardous waste, wastewater, or police departments for locations. Use the medicine manufacturer’s mail-back program if available.
3. Take leftover medicines to the Drug Enforcement Administration’s twice a year National Prescription Drug Take-back Days. Look for a site in your community at http://www.deadiversion.usdoj.gov/drug_disposal/takeback/ or contact your police department.
4. As a last resort, if there are no medicine take-back options in your community: put medicines in a sealed container in the trash after mixing the medicines with an undesirable substance, such as cat litter or used coffee grounds. Make sure the trash cannot be accessed by children, pets, or others who might be looking in garbage. Check with your local government or garbage service first, because local laws may not allow disposing of any pharmaceuticals in the trash.

We look forward to your response to our letter and to your actions to address our concerns.

Sincerely,

See Individual Sign-Ons below and Organizational Signers (in attached file, which will be merged for final version of letter)

Cc: Administrator Gina McCarthy, U.S. Environmental Protection Agency
Director Dan Ashe, U.S. Fish & Wildlife Service
Acting Administrator Chuck Rosenberg, Drug Enforcement Administration
Director Michael Botticelli, White House Office of National Drug Control Policy

Individual signers, affiliation stated for purposes of identification only.

Barbara J. Bickford, Madison, Wisconsin
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